

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

DEBORAH BARONE et al.,)	
)	
Plaintiffs,)	CASE NO. 4:20-CV-03950
)	
v.)	
)	
ETHICON, INC. and)	
JOHNSON & JOHNSON,)	
)	
Defendants.)	

**REPLY IN SUPPORT OF DEFENDANTS’ MOTION TO EXCLUDE CERTAIN
CASE-SPECIFIC OPINIONS OF DANIEL S. ELLIOTT, M.D.**

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, “Ethicon”) submit this Reply in support of the Motion to Exclude Certain Case-Specific Opinions of Daniel S. Elliott, M.D. (Doc. 141).

A. Dr. Elliott’s Specific Causation Opinions Are Unreliable Because He Did Not Perform a Reliable Differential Diagnosis.

Dr. Elliott’s purported differential diagnosis is unreliable because he did not explain how he ruled out any alternative causes of Ms. Barone’s injuries other than the mesh. Doc. 141 at 5–6. Plaintiffs argue it was enough that he set out a generic list of potential causes of injury, recited Ms. Barone’s medical history, and then concluded both TVT-O and Prolift caused Ms. Barone’s injuries. Doc. 149 at 5–7.¹ However, courts have made clear that “an expert does not establish the reliability of his techniques or the validity of his

¹ Plaintiffs also suggest that this argument was untimely, but fail to point to any order from this Court restricting the scope of Ethicon’s re-filed *Daubert* motions.

conclusions simply by claiming that he performed a differential diagnosis.” *McClain v. Metabolife Int’l, Inc.*, 401 F.3d 1233, 1253 (11th Cir. 2005). Indeed, a differential diagnosis that does not rule out alternative causes is “pure speculation.” *Cano v. Everest Minerals Corp.*, 362 F. Supp. 2d 814, 840 (W.D. Tex. 2005) (a differential diagnosis that does not rule out alternative causes is “pure speculation”).

Dr. Elliott’s recitation of generic causes of injury and Ms. Barone’s medical history may rule in certain other potential causes of her injuries, but it does nothing to rule out any of them. Nor is it sufficient that Dr. Elliott stated a conclusion that Ms. Barone’s mesh caused her injuries. Indeed, federal courts have rejected the concept of an “implicit” differential diagnosis. *Ronwin v. Bayer Corp.*, 332 F. App’x 508, 514 (10th Cir. 2009). Rather, an expert’s conclusion that alternative causes can be ruled out must be supported by “meaningful information about how he was able to exclude the many possible alternative causes of the problems.” *In re Breast Implant Litig.*, 11 F. Supp. 2d 1217, 1234 (D. Colo. 1998). In the absence of any explanation of how he ruled out any alternative causes, Dr. Elliott’s differential diagnosis is unreliable.

B. Dr. Elliott’s Opinions on Risks and Potential Complications That Ms. Barone Never Experienced Are Irrelevant.

Plaintiffs contend Dr. Elliott should be permitted to opine on irrelevant complications not at issue in this case because he is both a general and a case-specific expert, pointing out that the MDL Court did not preclude him from discussing these complications in generically ruling on the admissibility of his general opinions. Doc. 149 at 7–8. This misunderstands Ethicon’s argument, as well as the MDL Court’s prior ruling.

Complications Ms. Barone did not suffer are irrelevant *in this specific case*, and the MDL Court's prior ruling on global challenges to Dr. Elliott's general causation testimony across a group of cases does not address this issue. *See In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL No. 2327, 2016 U.S. Dist. LEXIS 117492, at *75 (S.D. W. Va. Aug. 26, 2016). By definition, Ethicon could not raise case-specific relevance challenges in the MDL when challenging an expert's general causation opinions. Rather, such challenges are appropriate for case-specific motions like this one. Because Plaintiffs fail to even address the relevance of these opinions, they should be excluded.²

Additionally, Dr. Elliott's opinions that Ms. Barone's dyspareunia may lead her to feelings of depression and suicide should be excluded as irrelevant because there was no evidence she had been treated for suicidal ideation and that any such risk was speculative. *See* Doc. 141 at 12. Plaintiffs point to a few mentions of depression in Ms. Barone's records, but fail to cite any records demonstrating she has experienced suicidal ideation. Doc. 149 at 9. While Plaintiffs contend Dr. Elliott is qualified to opine on Ms. Barone's future prognosis, they cannot point to any basis from which he could quantify her risk of suicide. Accordingly, this testimony is irrelevant and speculative.

C. Dr. Elliott's Opinion that Dr. Anhalt Was Unable to Secure Ms. Barone's Informed Consent Because of Alleged Deficiencies in the IFU Should Be Excluded Because It is Improper Expert Testimony, Speculative, and Irrelevant.

² Plaintiffs contend that this testimony could become relevant on rebuttal if Ethicon raises the issue of what other complications its mesh devices do or do not cause. Doc. 149 at 8–9. To the extent Ethicon introduces this testimony, this Court will be able to address whether Dr. Elliott's testimony would be relevant on rebuttal.

Dr. Elliott's opinion that Dr. Anhalt was unable to secure Ms. Barone's informed consent is inherently improper testimony on Dr. Anhalt's knowledge and state-of-mind. Doc. 141 at 10. Plaintiffs do not dispute that expert testimony on another person's knowledge is impermissible, but argue, paradoxically, that testimony on whether Dr. Anhalt knew enough to secure Ms. Barone's informed consent is admissible.

The MDL Court held that Dr. Elliott is qualified to "testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU." *In re Ethicon Inc.*, No. MDL No. 2327, 2018 U.S. Dist. LEXIS 241918, at *27 (S.D. W. Va. July 27, 2018). However, it also held "Dr. Elliott does not possess the additional expertise to offer expert testimony about what an IFU should or should not include." *Id.* This directly refutes Plaintiffs' contention that he "has specialized knowledge regarding whether the missing risk information [from an IFU] is of the sort that is significant enough to be necessary for adequately consenting a patient like [Ms. Barone]." Doc. 149 at 12. Dr. Elliott may testify about whether a certain risk of mesh procedures was included in an IFU, but he cannot take the additional step of opining on whether the absence of a risk from the IFU prevented Dr. Anhalt from knowing of that risk. *In re Ethicon, Inc.*, 2016 U.S. Dist. LEXIS 117492, at *90 (precluding Dr. Elliott from opining on another person's state-of-mind because it would "usurp the jury's fact-finding function"). Such testimony necessarily addresses Dr. Anhalt's knowledge.³

³ Plaintiffs urge this Court to follow a district court in California that recently allowed Dr. Elliott to opine on an implanting physician's knowledge. *See Parks v. Ethicon, Inc.*, No. 20-CV-989 TWR (RBB), 2020 U.S. Dist. LEXIS 192405, at *16 (S.D. Cal. Oct. 16, 2020) (allowing Dr. Elliott to opine that a physician "lacked information"). This Court should

Additionally, Plaintiffs have offered no substantive argument responding to Ethicon's reliability and relevance challenges to Dr. Elliott's testimony on Dr. Anhalt's knowledge of the risks and ability to secure informed consent. *See* Doc. 141 at 10–12. Ethicon's Motion should be granted as unopposed on these grounds.

D. Dr. Elliott's Opinions Regarding Native Tissue Repair and Coloplast Are Irrelevant and Unsupported.

Dr. Elliott's opinion that Ms. Barone's injuries could have been avoided if she had been treated with a native tissue repair is irrelevant, as Texas law requires Plaintiffs to demonstrate the existence of a safer alternative design for a product, rather than a different treatment option. Doc. 141 at 13–14. Plaintiffs claim this Court recently rejected this argument in *Bell v. Ethicon Inc.*, No. 4:20-CV-3678, 2021 U.S. Dist. LEXIS 54419 (S.D. Tex. Mar. 23, 2021), and ask this Court to follow that decision. Doc. 149 at 13–14. But Plaintiffs' claim that *Bell* allowed testimony on alternative procedures as evidence of safer alternative designs significantly misreads that decision. The *Bell* Court noted that, under Texas law, “[a] safer alternative design is both a statutorily required element of a design defect claim and a factor considered when conducting a risk-utility analysis to determine whether a product is unreasonably dangerous.” *Bell*, 2021 U.S. Dist. LEXIS 54419, at *18 (quoting *Flock v. Scripto-Tokai Corp.*, 319 F.3d 231, 239 (5th Cir. 2003)). Contrary to Plaintiffs' reading, the *Bell* Court did not find alternative procedures can satisfy the alternative design requirement under Texas law, but instead found that “[b]ecause Texas

decline to follow *Parks* where it contradicts the rulings of the MDL Court and basic principles on the parameters of expert testimony.

also applies a risk-utility analysis, the testimony on alternative surgical procedures is relevant and helpful to the jury as it informs whether the utility of the products at issue were outweighed by the risks in light of alternative treatments.” *Bell*, 2021 U.S. Dist. LEXIS 54419, at *18.

Ethicon disagrees with the *Bell* Court’s decision that different surgical procedures are relevant to the risk-utility analysis, as the Texas Supreme Court has explained that the relevant factor considers “the availability of a *substitute product* which would meet the same need and not be unsafe or unreasonably expensive.” *Am. Tobacco Co. v. Grinnell*, 951 S.W.2d 420, 432 (Tex. 1997). However, the issue is immaterial to Ethicon’s challenge in this case. Ethicon challenges Dr. Elliott’s opinion that a native tissue repair would have prevented Ms. Barone’s injuries if it had been used as an alternative to her mesh devices, not any testimony related to the risk-utility analysis. *See* Doc. 141 at 13–14. On this point, this Court has recently made clear that “[u]nder Texas law, Plaintiff must propose a safer and feasible alternative design to the alleged defective designs, not different procedures or strategies entirely.” *Pizzitola v. Ethicon, Inc.*, No. 4:20-CV-2256, 2020 U.S. Dist. LEXIS 205879, at *12 (S.D. Tex. Aug. 31, 2020). Indeed, Texas law is clear on this point. *See, e.g., Christopher v. DePuy Orthopaedics, Inc. (In re DePuy Orthopaedics, Inc.)*, 888 F.3d 753, 766 (5th Cir. 2018) (“The Texas Supreme Court and intermediate courts have held that a ‘substantially different product’ cannot constitute a safer alternative design.”). Dr. Elliott’s opinion that Ms. Barone’s injuries could have been avoided with a native tissue repair is irrelevant to this requirement.

Additionally, Dr. Elliott's opinion that Ms. Barone's injuries could have been prevented or significantly reduced by a Coloplast mesh product should be rejected as contrary to his testimony that all mesh products are unsafe, and because he failed to support this opinion. Doc. 141 at 14–16. Plaintiffs respond with a description of Dr. Elliott's general opinions on other products, but the reliability of Dr. Elliott's general opinions on other products is not at issue in this Motion. Plaintiffs also state generically that Dr. Elliott's opinions on Coloplast are "in line with these observations," but they fail to present any specific support for these opinions or, specifically, his conclusion that Coloplast would have "prevented or significantly reduced" Ms. Barone's alleged injuries. In fact, Dr. Elliott's general reports contain no discussion at all about Coloplast, apart from the statement that he does not think the product is safe. *See* Mot. Ex. E, Elliott General Prolift Report, at 1–2; Resp. Ex. L, Elliott General TVT-O Report. Dr. Elliott has no support for his Coloplast opinion, and it should be excluded.

E. Dr. Elliott's Case-Specific Opinions That Are The Same As His Previously Excluded General Opinions Should Be Excluded.

Plaintiffs do not contest that the MDL Court's rulings in *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL No. 2327, 2016 U.S. Dist. LEXIS 117492 (S.D. W. Va. Aug. 26, 2016) should control in this case. Doc. 149 at 16–17. While they contest Ethicon's characterization of pages 4–57 of Dr. Elliott's case-specific report, they do not dispute that the portions of that section that address Ethicon's knowledge or state-of-mind, or that simply parrot Ethicon documents, should be excluded.

CONCLUSION

FOR THESE REASONS, Ethicon respectfully prays that the Court grant its Motion to Exclude Certain Case-Specific Opinions of Daniel Elliott, M.D.

Respectfully submitted,

/s/ Christopher Cowan

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CERTIFICATE OF WORD COUNT

I hereby certify that the total word count of this reply is 1,987.

/s/ Christopher Cowan

Christopher R. Cowan

CERTIFICATE OF SERVICE

I hereby certify that on May 10, 2021, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

/s/ Christopher Cowan

Christopher R. Cowan